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18. (Amended) The layered film disk of claim 17, wherein said pharmaceutical or combination of pharmaceuticals comprises an anti-inflammatory analgesic agent, a steroidal anti-inflammatory agent, an antihistamine, a local anesthetic, a bactericide, a disinfectant, a vasoconstrictor, a hemostatic, a chemotherapeutic drug, an antibiotic, a keratolytic, a cauterizing agent, an antiviral, an antirheumatic, an antihypertensive, a bronchodilator, an anticholinergic, an antiemetic, a hormone, a macromolecule, a peptide, a protein, or a vaccine, alone or in combination.

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33. The carrier device of Claim 1 wherein the carrier device has a solvent content of from about 1 to about 15 % by weight.

REMARKS

Reconsideration is respectfully requested. Applicants have amended claim 1 to recite that the device "optionally" incorporates a pharmaceutical with the device. Support for this amendment can be found, among other places, at page 18, lines 15-18 of the instant specification. Claim 1 has also been amended to recite the polymers used in the first layer and second layer, i.e. "film-forming" and "bioadhesive," and "film-forming," respectively. Furthermore, Claim 16 has also been amended to correctly recite the hydrochloride salt of dyclonine as dyclonine "HCl". All dependent claims have also been respectively amended. These amendments have been made to more particularly point out and distinctly claim the subject matter which Applicants regard as their invention.

Rejection of Claim 16 under 35 U.S.C. § 101

Claim 16 was rejected under 35 U.S.C. § 101 as claiming the same invention as that of claim 3 of prior U.S. Patent No. 6,159,458. As an initial matter, Applicants assume that this rejection contains a typographical error and that the Examiner intended to refer to U.S. Patent

No. 6,159,498. If this is incorrect, please advise as to which U.S. patent is cited in this statutory double-patenting rejection. Assuming the statutory double-patenting rejection refers to U.S.

Patent No. 6,159,498, Applicants respectfully traverse this rejection.

Claim 3 of U.S. Patent No. 6,159,498 depends from claim 2, which in turn depends from claim 1. These claims read as follows:

1. A biodegradable, water-soluble pharmaceutical carrier device comprising a layered flexible film having a first water-soluble adhesive layer to be placed in contact with the mucosal surface and a second, water-soluble non-adhesive backing layer, and a pharmaceutical or combination of pharmaceuticals incorporated with said first or second layer, wherein said first water-soluble adhesive layer comprises hydroxyethyl cellulose, polyacrylic acid, and sodium carboxymethyl cellulose; and said second water-soluble non-adhesive backing layer comprises hydroxyethyl cellulose.
2. The pharmaceutical carrier device of claim 1, wherein said pharmaceutical or combination of pharmaceuticals comprises an anti-inflammatory analgesic agent.
3. The pharmaceutical carrier device of claim 2, wherein said anti-inflammatory analgesic agent is acetaminophen, methyl salicylate, monoglycol salicylate, aspirin, mefenamic acid, flufenamic acid, indomethacin, diclofenac, alclufenac, diclofenac sodium, ibuprofen, ketoprofen, naproxen, pranoprofen, fenoprofen, sulindac, fenclofenac, clidanac, flurbiprofen, fentiazac, bufexamac, piroxicam, phenylbutaxone, oxyphenbutaxone, clofezone, pentazocine, mepirizole, or tiaramide hydrochloride.

Claim 16 depends from claim 1. These pending claims as amended read as follows:

1. A pharmaceutical carrier device comprising a layered flexible film having a first water-erodable adhesive layer to be placed in contact with a mucosal surface, a second, water-erodable non-adhesive backing layer, and optionally a pharmaceutical incorporated with said first layer, said second layer, or both layers, wherein said first water-erodable adhesive layer comprises a film-forming polymer and a bioadhesive polymer, and wherein said second water-erodable non-adhesive backing layer comprises a film-forming polymer.
16. The pharmaceutical device of claim 1, wherein said first water-erodable adhesive layer comprises hydroxypropyl cellulose, hydroxyethyl cellulose, polyacrylic acid, and sodium carboxymethyl cellulose; said second water-erodable non-adhesive backing layer comprises hydroxyethyl cellulose and hydroxypropyl cellulose; and wherein said pharmaceutical comprises **dyclonine HCL** (emphasis added.)

The standard for determining whether a statutory basis for a double patenting rejection under 35 U.S.C. § 101 exists is whether the same invention is being claimed twice, wherein “same invention” means identical subject matter. M.P.E.P. 804-IIA. Instant claim 16 recites that **dyclonine HCl** is a pharmaceutical that can be included in the flexible layered film. In the ‘498 patent, **dyclonine HCl** is not one of the listed analgesic anti-inflammatory agents that is claimed in their pharmaceutical carrier device.

Thus, claim 16 of the instant invention and claim 3 of the ‘498 patent do not claim the “same invention” and the rejection of claim 16 for double-patenting under 35 U.S.C. §101 is improper. Accordingly, Applicants respectfully request that this rejection be withdrawn.

Rejection of Claims under 35 U.S.C. § 112 , Second Paragraph

Claims 1-10, 12, 13, 15-18, and 33 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicant regards as the invention. The Office Action states:

“In claims 1, 16 “CAPABLE” is vague; under what circumstances?
In claims 15, 17 “anticholigernic” is misspelled “antimenimic”
is indefinite. In claim 10 “derivatives” is vague; which ones?”

As an initial matter, Applicants assume that this rejection contains a typographical error and that the Examiner intended to refer to misspellings in claims 15 and 18, not 15 and 17. In addition, Applicants also assume that the rejection to claim 10 also applies to claim 13. Applicants request correction of the Office Action if this is incorrect.

In claim 1, “is capable of” has been amended to recite that a pharmaceutical is “optionally” incorporated with the device, and in claim 16, “capable” has been deleted. In claims 10 and 13, “derivatives” has been deleted to more particularly point out and distinctly

claim the subject matter of the Applicant's invention. In claims 15 and 18, "anticholigernic" has been replaced with "anticholinergic" and "antimenimic" has been replaced with "antiemetic", which are the correct spellings of the terms.

Thus, after entry of these amendments, Applicants submit that the amended claims meet the requirements of 35 U.S.C. § 112, second paragraph. Accordingly, Applicants respectfully request withdrawal of the rejection.

Rejection under 35 U.S.C. § 102(e)

Claims 1, 5, 6, 9, 11, 15, 17, 18, and 33 are rejected under 35 U.S.C. § 102(e) as being anticipated by Kamiya, et al. The Office Action states:

"Kamiya et al. teach a patch comprised of two water soluble layers (abstract). Antiseptics are specified (column 8 line 13). The Examiner notes that Kamiya et al. also reads on nonelected species in claims 3, 4, 11, 14 (see table 1). Disclosed (column 4 lines 60-67)."

Applicants respectfully disagree. Kamiya et al. teach a patch that is used during bathing. The patch adheres to dry skin and dissolves when immersed in bathwater to mimic the effects of a hot spring bath. The patch is comprised of a water-soluble adhesive sheet and a sheet of water-soluble protective material that is laminated thereon to the adhesive sheet. Kamiya, et al. do not teach or suggest that the patch may be "placed in contact with a mucosal surface" as required by independent claims 1 and 17 and those dependent thereon.

Thus, the instant invention is not anticipated by Kamiya, et al. and Applicants respectfully request reconsideration and withdrawal of the rejection.

Rejection under 35 U.S.C. § 112, First Paragraph

Claims 1-10, 12, 13, 15-18, and 33 are rejected under 35 U.S.C. § 112, first paragraph.

The Office Action states:

“Claims 1-10, 12, 13, 15-18, 33 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for a flexible film comprising two water erodible layers and containing a drug, the first layer being an adhesive layer comprising a film forming polymer, does not reasonably provide enablement for a layered film, wherein the water solubility is undefined (claim 17), not necessarily containing a drug (claim 1), and not necessarily claiming the recited polymers (claims 1, 17). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. The scope of applicants independent claims is broader than the disclosure (see page 6 lines 6-28).”

Applicants have amended claims 1 and 16 to define the instant invention by “what it is”, i.e. optionally containing pharmaceutical, rather than by functional language. Claims 1 and 17 have also been amended to recite the first and second water-erodable layers. The method for making the invention as claimed can be found in the specification at page 20 lines 17-27 and page 21 lines 1-10. These amendments have been made to more distinctly claim the invention described in the instant specification.

Therefore, reconsideration and withdrawal of the rejection is respectfully requested.

Rejection under 35 U.S.C. § 102 (b)

Claims 1, 5, 6, 9, 11, 19, 17, and 18 are rejected under 35 U.S.C. § 102 (b) as being anticipated by U.S. Patent 4,552,751 to Inaba, et al. As an initial matter, Applicants assume

that this rejection contains a typographical error and that the Examiner intended to refer to claims 1, 5, 6, 9, 15, 17, and 18 since Applicant is not aware of a claim 19. If this is incorrect, please advise to which claims are cited in this 35 U.S.C. §102 (b) rejection. The Office Action states:

“Inaba et al. teach a multilayered film comprising water soluble polymers (abstract). Prostaglandin E is specified (column 2 line 30). The Examiner notes that Inaba et al. discloses non-elected species reading on claims 2-4, 11, 14 (see column 2 lines 1-28, examples 1, 3).”

Assuming that the 102 (b) rejection refers to claims 1, 5, 6, 9, 11, 15, 17, and 18, Applicants respectfully traverse this rejection. Inaba, et al. teach a layered film that has at least three layers (two drug release controlling layers and one drug storing layer). Inaba, et al. does not suggest the use of two layers. Furthermore, Inaba, et al. do not teach an adhesive layer.” Thus, Applicants’ claimed film and that of Inaba, et al. are clearly different. Therefore, reconsideration and withdrawal of the rejection is respectfully requested.

SUMMARY

Applicants have responded to each matter of substance raised in this Office Action. Based on the arguments expressed here, applicants believe the case to be patentable and request that it be allowed.

In the event that there are any questions concerning this amendment or the application in general, the Examiner is respectfully urged to telephone the undersigned attorney so that prosecution may be expedited.

Attached hereto is a marked up version of the changes made to the claims by the current amendment. The attached page is captioned **“VERSION WITH MARKINGS TO SHOW CHANGES MADE.”** On this page, text additions have been underlined and brackets show text that has been deleted.

CONCLUSION

Applicants believe the application is in condition for allowance. In view of the above remarks, Applicants respectfully request the Examiner to withdraw all remaining rejections and allow this application.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, applicants petition for any required relief including extensions of time and authorize the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to: Deposit Account No. 03-1952 referencing docket no. 359872000821. However, the Assistant Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

1. (Amended) A pharmaceutical carrier device comprising a layered flexible film having a first water-erodable adhesive layer to be placed in contact with a mucosal surface, [and] a second, water-erodable non-adhesive backing layer, and optionally [wherein said device is capable of having] a pharmaceutical incorporated with [in] said first layer, said second layer, or both layers, wherein said first water-erodable adhesive layer comprises a film-forming polymer and a bioadhesive polymer, and wherein said second water-erodable non-adhesive backing layer comprises a film-forming polymer.

2. The pharmaceutical carrier device of claim 1, wherein said first water-erodable layer comprises an alkyl cellulose or hydroxyalkyl cellulose and a bioadhesive polymer.

3. The pharmaceutical carrier device of claim 1, wherein said first water-erodable adhesive layer comprises a film forming polymer selected from hydroxyethyl cellulose, hydroxypropyl cellulose, hydroxypropylmethyl cellulose, hydroxyethyl methyl cellulose, polyvinyl alcohol, polyethylene glycol, polyethylene oxide, ethylene oxide-propylene oxide co-polymers, collagen and derivatives, gelatin, albumin, polyaminoacids and derivatives, polyphosphazenes, polysaccharides and derivatives, or chitin and chitosan, alone or in combination, and a bioadhesive polymer selected from polyacrylic acid, polyvinyl pyrrolidone, or sodium carboxymethyl cellulose, alone or in combination.

4. The pharmaceutical carrier device of claim 1, wherein said second water-erodable non-adhesive backing layer comprises hydroxyethyl cellulose, hydroxypropyl cellulose, hydroxyethylmethyl cellulose, hydroxypropylmethyl cellulose, polyvinyl alcohol, polyethylene glycol, polyethylene oxide, or ethylene oxide-propylene oxide co-polymers, alone or in combination.

5. (Amended) The pharmaceutical device of claim 1, wherein a pharmaceutical is incorporated with [present in] said first water-erodable adhesive layer.

6. The pharmaceutical device of claim 1, wherein said layered film has two layers and a total thickness of from 0.1 mm to 1 mm.

7. The pharmaceutical device of claim 1 which further comprises a third layer between said first adhesive layer and said second backing layer and wherein said third layer is a water-erodable, adhesive layer which has a surface area sufficient to encompass said first adhesive layer and contact the mucosal surface.

8. (Amended) The pharmaceutical device of claim 7, wherein a pharmaceutical is incorporated with [present in] said first adhesive layer.

9. The pharmaceutical device of claim 1, wherein one or more of the layers further comprises a component which acts to adjust the kinetics of the erodability of the device.

10. (Amended) The pharmaceutical device of claim 9 wherein the component is a water-based emulsion of polylactide, polyglycolide, lactide-glycolide copolymers, poly-ε-caprolactone [and derivatives], polyorthoesters [and derivatives], polyanhydrides [and derivatives], ethyl cellulose, vinyl acetate, cellulose acetate, or polyisobutylene, alone or in combination.

11. The pharmaceutical device of claim 9 wherein the component is alkyl-glycol, propylene glycol, polyethyleneglycol, oleate, sebacate, stearate or esters of glycerol, or phthalate.

12. The pharmaceutical device of claim 7, wherein one or more of the layers further comprises a component which acts to adjust the kinetics of the erodability of the device.

13. (Amended) The pharmaceutical device of claim 12 wherein the component is a water-based emulsion of polylactide, polyglycolide, lactide-glycolide copolymers, poly-ε-caprolactone [and derivatives], polyorthoesters [and derivatives], polyanhydrides [and

derivatives], ethyl cellulose, vinyl acetate, cellulose acetate, or polyisobutylene, alone or in combination.

14. The pharmaceutical device of claim 12 wherein the component is alkyl-glycol, propylene glycol, polyethyleneglycol, oleate, sebacate, stearate or esters of glycerol, or phthalate.

15. (Amended) The pharmaceutical device of claim 1, wherein said pharmaceutical [capable of being] incorporated within said first layer, said second layer, or both layers comprises an anti-inflammatory analgesic agent, a steroidal anti-inflammatory agent, an antihistamine, a local anesthetic, a bactericide, a disinfectant, a vasoconstrictor, a hemostatic, a chemotherapeutic drug, an antibiotic, a keratolytic, a cauterizing agent, an antiviral, an antirheumatic, an antihypertensive, a bronchodilator, an anticholinergic [anticholinergic], an antiemetic [antimenimic compounds], a hormone, a macromolecule, a peptide, a protein, or a vaccine alone or in combination.

16. (Amended) The pharmaceutical device of claim 1, wherein said first water-erodable adhesive layer comprises hydroxypropyl cellulose, hydroxyethyl cellulose, polyacrylic acid, and sodium carboxymethyl cellulose; said second water-erodable non-adhesive backing layer comprises hydroxyethyl cellulose and hydroxypropyl cellulose; and wherein said pharmaceutical [capable of being incorporated] comprises dyclonine HCl [HCl].

17. (Amended) A layered flexible film disk which adheres to mucosal surfaces for the localized delivery of pharmaceutical, comprising a first adhesive layer and a second non-adhesive backing layer, wherein said pharmaceutical or combination of pharmaceuticals is incorporated with [present in] said first adhesive layer, or said second non-adhesive backing layer, or both said first adhesive layer and said second non-adhesive backing layer, and wherein said first water-erodable adhesive layer comprises a film-forming polymer and a bioadhesive polymer, and wherein said second water-erodable non-adhesive backing layer comprises a film-forming polymer, said layered flexible film having a total thickness of from 0.1 mm to 1 mm.

18. (Amended) The layered film disk of claim 17, wherein said pharmaceutical or combination of pharmaceuticals comprises an anti-inflammatory analgesic agent, a steroidal anti-

inflammatory agent, an antihistamine, a local anesthetic, a bactericide, a disinfectant, a vasoconstrictor, a hemostatic, a chemotherapeutic drug, an antibiotic, a keratolytic, a cauterizing agent, an antiviral, an antirheumatic, an antihypertensive, a bronchodilator, an anticholinergic [anticholigernic], an antiemetic [antimenimic compounds], a hormone, a macromolecule, a peptide, a protein, or a vaccine, alone or in combination.

33. The carrier device of Claim 1 wherein the carrier device has a solvent content of
from about 1 to about 15 % by weight.